UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Review of the Ecolab Inc. Registration Request for the Use of Hydrogen Peroxide and Peroxyacetic Acid as a Seed Treatment

TO: Product Manager Team 33
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CASE NO.: 046821

PC CODE: 063201 Peroxyacetic Acid
000595 Hydrogen Peroxide

MRID NO.: 452790-00

Introduction:

Ecolab Inc. has submitted an application for registration for the use of a product identified as Oxy-15 for use as a seed treatment. The active ingredients on the label are peroxyacetic acid and hydrogen peroxide. The product registration number on the label is EPA Reg. No. 1677-164.

Background:

There are a large number of uses for the active ingredients, hydrogen peroxide and peroxyacetic acid, under both FDA 21 CFR and EPA 40 CFR Titles. Under the 40 CFR 180.1196 and 180.1197, there are uses for both chemicals on food commodities and on food contact surfaces.

RASSB has recently reviewed a Section 18 for the use of these chemicals as a seed treatment for use on cucurbits under the EPA Reg. No. 1677-164 under the name of Tsunami 100.

Conclusions:

1. Under the conditions of use proposed on the Oxy-15 label and based on the data submitted, RASSB concludes that the proposed use is a non-food use.

2. Based on the known chemical and physical propeties of hydrogen peroxide and peroxyacetic acid and on the residue study submitted, RASSB concludes that there is no likelihood of residues of either hydrogen peroxide or peroxyacetic acid occuring in plants grown from treated seed.

3. Because RASSB considers the proposed use to be a non-food use, there will be no problem of secondary residues occuring in meat, milk poultry or eggs from the proposed use.

Recommendations:

RASSB has no objection to the issuance of the requested registration for the proposed use of this Oxy-15 formulation as a seed treatment.

The label title should, however, be revised as recommended below under the Proposed Use section to include the seed treatment use. The present label title addresses use only on "Fresh Cut, Post Harvest, and Further Processed Fruits and Vegetables" - not for the proposed seed treatment use.

Detailed Considerations

OPPTS GLN 860.1100 Chemical Identity

The name of the product is Oxy -15. The product contains 15.0% peroxyacetic acid and 11.0% hydrogen peroxide.

The active ingredients in the formulation are:

Component(CAS No.)	Empirical Formula	Structural Formula	Formula Weight
Hydrogen Peroxide(7722-84-1)	H_2O_2	H-O-O-H	34
Peroxyacetic Acid(79-21-0)	$C_2H_4O_3$	H_3-C-C-O-OH ‖ O	75

OPPTS GLN 860.1200 Proposed Use

The proposed use of the Oxy-15 product is as a treatment to seeds not intended for human or animal consumption to control seedbourne microorganisms that cause plant disease or spoilage and decay of developing seedlings. Presumably, the use could be for treatment of any seed intended for planting, either as a food crop or as an ornamental.

The label title should be revised to include the seed treatment use because the label submitted states that the product is a " Water Additive for Controlling the Growth of Microorganisms that cause decay and spoilage On Fresh Cut, Post Harvest, and Further Processed Fruits and Vegetables in transport, storage and processing". The use as a seed treatment is not included in the label heading.

The product is to be mixed with water to produce a solution containing 1600 ppm of peroxyacetic acid.(Note: The solution would also contain 1173 ppm of hydrogen peroxide.)

Seeds should be submerged in the treatment solution for 30 minutes. Seeds should then be removed from the treatment solution and dried.

The label use directions for the seed treatment state that use is, "For Treatment Of Seeds not Intended For Human Or Animal Consumption". The registrant has confirmed that this statement is intended to mean that humans and animals should not directly consume the treated seed-but that humans and animals can consume the plants grown from treated seed(Telecon between Dr. Brian Brosdahl, Ecolab, Inc. and R. Quick, RASSB/EPA on 2/6/2001.

OPPTS GLN 860.1500 Residue Chemistry

The residue chemistry guidelines offer guidance for food use/nonfood use determination under OPPTS GLN 860.1000(e)(2)(*ii*) for seed treatments. This includes cases where seed is treated either by the seed company(and dyed according to 40 CFR 153.155) or by the farmer(planter box or hopper treatments). In order for a seed treatment to be considered to be a non-food use, data from a radiotracer study must be available showing no uptake of residues (radioactivity) from treated seed into the aerial portion of the growing crop.(Note: the HED Chem SAC issued guidance on the required level of quantitation to make a determination of no uptake of residues

into the aerial portion of the plant grown from treated seed as being 5 ppb.) . If residues occur in the aerial portion of the plant or if there are no data to make this determination, seed treatments are considered to be food uses requiring tolerances. Factors affecting this include the level of residues on the harvested seed, the half-life of seed residues and the weight of the seed in relation to that of the subsequent crop.

For the proposed registration of this Ecolab, Inc. product, treatment is to be made with a formulation containing peroxyacetic acid and hydrogen peroxide. Both of these chemicals are easily degraded by heat, sunlight, traces of heavy metals either in the ionic or finely divided state, ferments, enzymes or many kinds of dust and dirt.

A seed treatment residue study was submitted to the Agency to support the registration of this product as a seed treatent. The study is entitled, "Residual Concentration Of Peroxyacetic Acid And Hydrogen Peroxide On Cantaloupe Seeds Washed With Tsunami® 100", MRID #452790-01, Study Director and Principal Chemist: John Hilgren. The study is not a GLP study.

The study involved the following:

- A seed/pulp mixture was taken from cantaloupe melons on 5/4/2000.
- Approximately 200 gram quantities of the mixture were taken and stored in plastic bags under ambient conditions.
- On 5/5/2000, the contents were placed in an open beaker and allowed to ferment at 25-30°C.
- On 5/8/2000, the seeds were washed with deionized water. Seeds that sank were separated and used for testing. The remainder were discarded.
- Approximately 2552 seeds were placed in a nylon mesh bag(This number was based on adding 136 grams of seeds at an average weight of 0.0553 gram). The mesh bag was placed in beakers containing 600 ml of a *Tsunami 100* use solution containing peroxyacetic acid and hydrogen peroxide. The approximate volume of 2552 seeds was 200 ml.
- Seeds were soaked with *Tsunami 100* solutions containing peroxyacetic acid at concentrations of 800, 1600 and 3200 ppm and containing hydrogen peroxide at concentrations of 610 ppm, 1200 ppm and 2450 ppm for 30 minutes and stirred to ensure uniform exposure. Treated seeds were separated from the use solution using a strainer. The use solution was discarded.
- Treated seeds were either rinsed twice for 5 minutes with 600 ml of deionized water and placed in an incubator at 100°C. to dry for 4 hours or allowed to dry directly without a rinse.(The latter reflecting no rinse would reflect the proposed use pattern.)

- After drying, approximately 2294 grams of seeds were placed in 100 ml of deionized water and and mixed in a Stomacher mixer for 2 minutes to extract residual peroxyacetic acid and hydrogen peroxide.

- After mixing, the extraction water was tested for peroxyacetic acid and hydrogen peroxide using a Tsunami Test Kit. The residue of peroxyacetic acid and hydrogen peroxide was determined on each seed. Data were also reported for seeds that were both rinsed and unrinsed with water.

The registrant reports that residues of peroxyacetic acid and hydrogen peroxide in the extraction water from the treated seeds were less than 1 ppm from both the rinsed and the unrinsed seed. Residues in the dry treated unrinsed seed are reported as less than 0.0004 ppm. RASSB concludes that residues of peroxyacetic acid and hydrogen peroxide do not persist on the unrinsed treated seed. There are no residue data reported for melons grown from the treated seed.

RASSB comments on the study:

1. The seed treatment study was not a radiotracer study for the peroxyacetic acid.
2. The treated seeds were not used to grow plants which could be analyzed for residues.
3. There is no description of the Tsunami test method that was used for the analysis of peroxyacetic acid and hydrogen peroxide.
4. There are no data submitted to validate the test method(control values and recovery data) at the levels of quantitation that are implied by the residue data.

Even though the available residue data do not meet the criteria described in OPPTS GLN 860. 1000 as a non- food use, RASSB concludes that because no residues(<0.004 ppm) of either chemical were detected in treated seed and because of the chemical nature of these two active ingredients, there is no likelihood of residues resulting in plants grown from treated seed. Degradation products would be expected to be acetic acid and water from peroxyacetic acid and to be water and oxygen from hydrogen peroxide.

RASSB concludes that the proposed use is a nonfood use. RASSB consultation with Dr. Rick Loranger, Senior Scientist in the Health Effects Division, confirmed this opinion.